

DEPARTMENT OF FOOD AND AGRICULTURE

INITIAL STATEMENT OF REASONS

Hearing Date: No hearing is scheduled for this proposal. A public hearing will be held if any interested person, or his or her duly authorized representative, submits a written request for a public hearing to the Department of Food and Agriculture (Department) no later than 15 days prior to the close of the written comment period.

Subject Matter of Proposed Regulations: Bovine Brucellosis
Movement of Swine
Quarantine

Sections Affected: Amend sections 752, 796.6, and 1301

Specific Purpose of Each Adoption, Amendment, or Repeal

The Department is amending three separate sections under Title 3 of the California Code of Regulations.

The first proposal pertains to Food and Agricultural Code section 10327, which authorizes the Department to establish the conditions for the movement of female dairy cattle as evident through calfhood vaccination or other tests to prevent outbreaks and the spread of bovine brucellosis. In compliance with section 10327, the Department has in place existing bovine brucellosis regulations under Article 1.5 (Bovine Brucellosis) of Chapter 2, Division 2, of Title 3 of the California Code of Regulations. This proposal amends section 752 (Vaccine, Vaccination, and Test Reagents) of Article 1.5 to update the vaccination age of female dairy heifers age for consistency with the vaccine manufacturers recommendation.

The second proposal pertains to Food and Agricultural Code section 10781, which authorizes the Department to adopt regulations to control swine diseases through limitations on their movement into and within California. In compliance with section 10781, the Department has in place existing swine movement regulations under Article 8.5 (Interstate and Intrastate Movement of Swine) of Chapter 2, Division 2, of Title 3 of the California Code of Regulations. This proposal amends section 796.6 (Movement of Swine into California for Immediate Slaughter) of Article 8.5 to require an Interstate Livestock Entry Permit when the State Veterinarian determines a risk exists with the importation of swine into California.

The third proposal pertains to Food and Agricultural Code section 9562, which authorizes the State Veterinarian to quarantine or restrict the movement of animals or animal products to minimize the risk of an illness that could kill or seriously damage other animals or humans. In compliance with sections 9562, the Department has in place existing Quarantine regulations under Article 3 (Quarantine) of Chapter 7, Division 2, of Title 3 of the California Code of Regulations. This proposal adds a definition to section 1301

(Definitions) of Article 3 to enhance the use of professional judgment, as delegated by the State Veterinarian, to determine when a population of animals may carry a disease.

The overall intent of these regulation changes is to make necessary amendments and additions to clarify existing regulations in an effort to further prevent and control the spread livestock diseases in California and the United States.

Factual Basis

The Department is responsible for promoting and protecting the agricultural industry of California. Further, the Department seeks to enhance, protect and perpetuate the ability of the agricultural industry to produce food and fiber in a way that benefits the general welfare and economy of California, and maintains the economic well-being of agriculturally dependent rural communities in California pursuant to Food and Agricultural Code sections 401 and 401.5.

The Department's Animal Health Branch is the State's organized, professional veterinary medical unit that protects livestock populations, consumers, and California's economy from catastrophic animal diseases and other health or agricultural problems. The Branch addresses diseases and other problems that cannot be successfully controlled on an individual animal or herd basis, but require statewide coordinated resources.

This proposal contains three separate changes to existing regulations under Articles 1.5 and 8.5 of Chapter 2, and Article 3 of Chapter 7, of Division 2 of Title 3 of the California Code of Regulations. The factual basis and rationale for each proposal is detailed below.

1) Bovine Brucellosis.

Amend Section 752. Vaccine, Vaccination, and Test Reagents.

Pursuant to Food and Agricultural Code section 10327, the Animal Health Branch has in place existing regulations for vaccinating female cattle against bovine brucellosis in an effort control and eradicate the disease. Brucellosis is a contagious disease of livestock that also affects humans. The disease is also known as contagious abortion or Bang's disease in livestock. In humans, it is known as undulant fever because of the intermittent fever accompanying infection. It is one of the most serious diseases of livestock, because it spreads so rapidly and it is transmissible to humans.

California currently requires all female dairy cattle to be vaccinated with an approved *Brucella* vaccine. The vaccine is a live product and must be administered only by an accredited veterinarian or State or Federal animal health officials. At the time of vaccination, a tattoo is applied in the ear identifying the animal as an official vaccinee and indicates the year which vaccination took place. Vaccination is not 100-percent effective in preventing brucellosis, however it protects about 65 percent of the vaccinated cattle from becoming infected by an average exposure to *Brucella*. Some states, including California, do not allow cattle and bison to be imported for breeding if they are not official vaccinees and they are beyond the age at which they should have been vaccinated.

This proposal amends subsection (c) for the official brucellosis calfhood vaccination age for female dairy heifers to be consistent with the manufacturers recommended age. The current age at which female dairy cattle are vaccinated is between the ages of 4 and 8 months, and beef cattle between 4 and 12 months. The difference in ages between the two types of cattle is because dairy cattle tend to mature at a younger age than beef cattle; in order to prevent brucellosis infection, vaccination should begin before the animal is old enough to bare young.

Currently, the Department allows the vaccination of both dairy and beef female cattle with two different vaccines, Strain 19 and RB-51. Existing regulations state the recommended vaccination age for dairy cattle to be conducted between 4 and 8 months of age. Colorado Serum Company and its subsidiary Professional Biological Company, the manufacturer and supplier of RB-51, recommends the vaccination of all female cattle to be between the ages of 4 and 12 months of age. Although the Department provides for the use of both vaccines, RB-51 is exclusively used in California. Therefore, to be consistent with the manufacturer's recommendations, the Department is proposing to change the vaccination age for female dairy cattle to 4 to 12 months of age.

2) Movement of Swine.

Amend Section 796.6. Movement of Swine into California for Immediate Slaughter.

Pursuant to Food and Agricultural Code section 10781, the Department has in place existing regulations to control swine diseases (swine brucellosis and pseudorabies) by limiting their movement into and within the State. The interstate movement requirements for swine brucellosis and pseudorabies include Interstate Livestock Entry Permits and blood testing, and related information necessary to monitor shipments of swine, assure compliance, and locate exposed or infected swine to decrease the probability that infected swine will be imported into California.

Swine brucellosis is a serious disease causing weight loss, loss of young, infertility, and lameness. The rapidity with which it spreads and the fact that it is transmissible to humans makes it all the more serious. Unfortunately, there is no treatment for the disease and no vaccine to prevent infection. Surveillance and the state's importation requirements for swine entering California from other states are the best defense for preventing the introduction and spread of the disease.

Pseudorabies is a disease of swine that can also affect cattle, horses, dogs, cats, sheep, and goats. The disease is an extremely contagious herpes virus that causes reproductive problems, including abortion, stillbirths, and even occasional death losses. Pseudorabies can be prevented primarily through biosecurity, vaccination, and thorough herd management practices. Current regulations to control and eradicate pseudorabies include interstate movement restrictions on swine entering California from other US states.

This proposal amends subsection (b)(1) by requiring a person importing slaughter swine into California to obtain an Interstate Livestock Entry Permit.

Currently, to prevent swine brucellosis and pseudorabies, the Department allows this classification of swine to enter the state only after receiving permission granted via an Interstate Livestock Entry Permit issued by the Animal Health Branch. However, the successful progression of national eradication programs for both swine brucellosis and pseudorabies have lead the Department to reevaluate importation regulations imposed on persons importing swine into California for immediate slaughter.

The Department has determined that the existing requirements for slaughter swine may be too restrictive and do not allow for any flexibility when the probability of infection is low or nonexistent. For instance, all US states are considered to be free of Pseudorabies in commercial production herds by the USDA, and have attained Stage IV of Free status as determined by the national Pseudorabies Eradication Program. Although sporadic infections do still occur, the demands imposed on persons importing animals from areas free of disease should be realistic.

In the case of swine brucellosis, successful eradication efforts leave only one US state classified as State II, a level only one step below establishing Free status. Because the immediate threat for disease introduction is low, although still possible, the Department is proposing to amend the regulations to allow for flexibility when requiring persons importing swine to obtain an Interstate Livestock Entry Permit.

Compliance with existing regulations requires persons importing swine for immediate slaughter to obtain an Interstate Livestock Entry Permit from the Animal Health Branch before animals leave the premises of origin. Persons importing the swine telephone the Department and supply the required information for the Permit. The Department grants permission for the livestock to enter the State by issuing the importer an Interstate Livestock Entry Permit Number. Information given to the Department for the permit is important as it can be used to track animal movements and locate specific animals should a disease outbreak occur.

Because current disease threat for swine brucellosis and pseudorabies is extremely low, the Department is proposing to amend the regulations to no longer require a permit for all slaughter swine entering California. Instead, if the State Veterinarian believes a threat for disease exists with the shipment, in the originating state or any location the animals are shipped from or have been, a Permit may be required. Criteria used to make this determination could include the national or state disease status, standard epidemiological research or credible scientific research. This proposal also recommends persons importing swine for immediate slaughter to contact the Animal Health Branch prior to shipment to verify if the permit is required. Persons importing slaughter swine can also verify the requirements for importation all livestock by viewing the Department's Internet Website where entry requirements for all species of animals are available.

The Department believes these changes are necessary as they would allow for flexibility to persons importing swine for immediate slaughter by requiring a Permit only when the threat for disease is high – not continually, and without exception as the regulations now read.

3) Quarantine.

Amend Section 1301. Definitions.

Food and Agricultural Code section 9562 authorizes the State Veterinarian to quarantine or restrict the movement of animals or animal products to minimize the risk of an illness that could kill or seriously damage other animals or humans. In compliance with section 9562, the Department has in place existing quarantine regulations under sections 1301 through 1301.9 of Article 3 (Quarantine) of Chapter 7, Division 2, of Title 3 of the California Code of Regulations. This proposal adds a new definition to further clarify the conditions under which the State Veterinarian shall impose quarantine.

The quarantine regulations look at quarantine, not as an action to be taken, but as an acknowledgment that a risk is present somewhere, and that the State Veterinarian shall take the necessary measures to intervene and prevent the problem from becoming a serious situation. Such actions may include holding, isolating, or destroying animals or animal products. Quarantine regulations also define the ability to order the recall of an animal product already shipped or for the return of animals to their origin, and provide for the Appeal and Hearing Rights of a person under such order.

Section 1301 defines the terms used in Article 3 (Quarantine). This proposal adds subsection (z) to define the term “may carry” as referenced in Food and Agricultural Code section 9562, to mean that in the exercise of the State Veterinarian's professional judgment, "susceptible to" or a belief that a population of animals or animal product has a condition pending epidemiological investigation.

The Department believes this addition is necessary as it further clarifies and specifically defines “may carry”, putting more emphasis on the chance that a disease could possibly exist. The phrase “may carry” may have a general meaning to the public, whereas the Department's interpretation is dependent on the State Veterinarian's professional judgment.

Underlying Data

Information on the Colorado Serum Company *Brucella abortus* Vaccine Strain RB-51.

Business Impact

The Department has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting California businesses, including the ability of California businesses to compete with businesses in other states. This proposal pertains to the vaccination age of female dairy cattle, removes the requirement to obtain an Interstate Livestock Entry Permit for slaughter swine entering California, and clarifies the Department's interpretation of the term “may carry” as referenced in Food and Agricultural Code section 9562. This proposal imposes the following paperwork, recordkeeping and reporting requirements upon businesses:

1) Paperwork: This proposal contains paperwork requirements consisting of brucellosis vaccine used for brucellosis calfhood vaccination, and eartags used for identifying vaccinated cattle. All female beef and dairy cattle are required to be vaccinated for brucellosis and shall maintain an identification eartag and tattoo declaring the animal as a vaccinated animal. This proposal amends the age at which vaccination is required for dairy cattle. This change will not have an affect on existing costs for vaccinating and identifying cattle.

2) Record Keeping: This proposal does not contain a record keeping requirement. However, veterinarians vaccinating cattle against brucellosis are required to report specified information to the Department. Information required to be reported is maintained by the Department for purposes of tracing animals in the event of a disease outbreak. Veterinarians may keep records of vaccinations conducted by their businesses, and persons owning cattle may also keep copies of these records. These processes could therefore be considered a record.

3) Reporting: This proposal contains reporting requirement consisting of the use of all vaccines for brucellosis calfhood vaccination and eartags used for identification. Costs for compliance with this requirement are existing costs; the proposed change of vaccination age would not have any affect on these existing costs.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment; however, the livestock industry or veterinary medical practices may require specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Department of Food and Agriculture would either be more effective in carrying out the purpose for which the action is proposed or would be as effective as and less burdensome to affected private persons than the proposed regulation.